Operator's Manual

2022105-201rC

REVISION HISTORY		
Part number	**Date**	**Comment**
2022105-201 Rev A	October 2006	Initial Release
2022105-201 Rev B	December 2006	AHA Guidelines added
2022105-201 Rev C	July 2007	Revised for misc. minor updates, new symbols and EMC table added

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SECTION 1: INTRODUCTION

OVERVIEW

Become familiar with the controls and how to use the AED properly before operating the product.

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INDICATIONS FOR USE/INTENDED USE

The AED with STAR Biphasic Waveform is intended to be used by personnel who have been trained in its operation. The operator should be qualified by training in basic life support, CPR/AED or other physician-authorized emergency medical response. The device is indicated for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest that are unresponsive and not breathing. If the victim is breathing post-resuscitation, the AED should be left attached to allow for acquisition and detection of the ECG rhythm. If a shockable ventricular tachyarrhythmia recurs, the device will charge automatically and advise the operator to deliver therapy.

WARNING: When the patient is a child or infant under 8 years of age or weighs less than 55 lbs (25kg), the AED should be used with the Model 9730 Pediatric Attenuated Defibrillation Electrode Pads. Therapy should not be delayed to determine the patient's exact age or weight.

AED DESCRIPTION

The AED is a self-testing, battery-operated automated external defibrillator (AED). After applying the AED pads to the patient's chest, the AED automatically analyzes the patient's electrocardiogram (ECG) and advises the operator to push the button and deliver a shock if needed. The AED uses one button and guides the operator through the rescue using a combination of voice prompts, audible alerts, and visible indicators.

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SAFETY TERMS AND DEFINITIONS

BEFORE OPERATING THE RESPONDER AED

Become familiar with the various safety alerts in this section.

Safety alerts identify potential hazards using symbols and words to explain what could potentially harm you, the patient, or the Responder AED.

SAFETY TERMS AND CONDITIONS

The triangle attention symbol shown below, left, identifies the potential hazard categories. The definition of each category is as follows:

DANGER: This alert identifies hazards that will cause serious personal injury or death.

WARNING: This alert identifies hazards that may cause serious personal injury or death.

CAUTION: This alert identifies hazards that may cause minor personal injury, product damage, or property damage.

SAFETY ALERT DESCRIPTIONS

The following is a list of Responder AED safety alerts that appear in this section and throughout this manual. You must read, understand, and heed these safety alerts before attempting to operate the AED.

DANGER: Fire and Explosion Hazard
Do not use the AED in the presence of flammable gases (including concentrated oxygen) to avoid possible explosion or fire hazard.

WARNING: Shock Hazard
Defibrillation shock current flowing through unwanted pathways is potentially a serious electrical shock hazard. To avoid this hazard during defibrillation abide by all of the following:

- Do not touch the patient, unless performance of CPR is indicated
- Do not touch metal objects in contact with the patient
- Keep defibrillation pads clear of other pads or metal parts in contact with patient
- Disconnect all non-defibrillator proof equipment from the patient before defibrillation

WARNING: Shock and Possible Equipment Damage
Disconnect all non-defibrillator proof equipment from the patient before defibrillation to prevent electrical shock and potential damage to the equipment.

WARNING: Electric Shock and Fire Hazard
Do not connect any telephones or unauthorized connectors to the socket on this equipment.

WARNING: Battery is Not Rechargeable
Do not attempt to recharge the battery. Any attempt to recharge the battery may result in an explosion or fire hazard.

WARNING: Shock Hazard
Do not disassemble the AED! Failure to observe this warning can result in personal injury or death. Refer maintenance issues to authorized service personnel.

CAUTION: Temperature/Humidity/Pressure Extremes
Exposing the AED to extreme environmental conditions outside of its operating parameters may compromise the ability of the AED to function properly. The RescueReady® daily self-test verifies the impact of extreme environmental conditions on the AED by checking temperature, humidity and pressure; if the daily self-test determines environmental conditions outside of the AEDs operating parameters for 5 consecutive days, a "SERVICE REQUIRED" alert will be issued to prompt the user to move the AED to environmental conditions within the acceptable operating parameters at once. See Section 6 – Technical Data, Parameters, Operation and Standby Conditions.

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CAUTION: Lithium Sulfur Dioxide Battery
Pressurized contents: Never recharge, short circuit, puncture, deform, or expose to temperatures above 65°C (149°F). Remove the battery when discharged.

CAUTION: Battery Disposal
Recycle or dispose of the lithium battery in accordance with all federal, state and local laws. To avoid fire and explosion hazard, do not burn or incinerate the battery.

CAUTION: Use only GE Approved Equipment
Using batteries, pads, cables, or optional equipment other than those approved by GE may cause the AED to function improperly during a rescue.

CAUTION: Possible Improper AED Performance
Using pads that are damaged or expired may result in improper AED performance.

CAUTION: Serial Communication Cable
The AED will not function during a rescue when the serial communication cable is connected to its serial port. When the serial communication cable is connected to the AED during a rescue, the prompt "Remove Cable to Continue Rescue" will be heard until you remove the serial communication cable.

CAUTION: Possible Radio Frequency (RF) Susceptibility
RF susceptibility from cellular phones, CB radios and FM 2-way radio may cause incorrect rhythm recognition and subsequent shock advisory. When attempting a rescue using the AED, do not operate wireless radiotelephones within 1 meter of the AED – turn power OFF to the radiotelephone and other like equipment near the incident.

CAUTION: Possible Interference with Implanted Pacemaker
Therapy should not be delayed for patients with implanted pacemakers and a defibrillation attempt should be made if the patient is unconscious and not breathing. The AED has pacemaker detection and rejection, however, with some pacemakers the AED may not advise a defibrillation shock.[1]

Placing Pads:
- Do not place the pads directly over an implanted device.
- Place the pad at least one inch from any implanted device.

CAUTION: Moving the Patient During a Rescue
During a rescue attempt, excessive jostling or moving of the patient may cause AEDs to improperly analyze the patient's cardiac rhythm. Stop all motion or vibration before attempting a rescue.

CAUTION: Serial Communication Cable
The serial communication cable is only for use with the AED; it is not to be used with a telephone.

CAUTION: Systems Statement
Equipment connected to the analog and digital interfaces must be certified to the respective IEC Standards (i.e. IEC 60950-1 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standard IEC 60601-1-1. Anybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore, responsible that the system complies with the requirements of the system standard IEC 60601-1-1.

CAUTION: Case Cleaning Solutions
When disinfecting the case, use a non-oxidizing disinfectant, such as ammonium salts or a glutaraldehyde based cleaning solution, to avoid damage to the metal connectors.

CAUTION: The AED is programmed with software that has been tested to work with versions of ServiceLink and RescueLink that are included with the AED. When older versions of ServiceLink and RescueLink are used to communicate with this AED, there may be features described in this manual that are not available to be used. Also, when communicating with an older AED with the version of ServiceLink and RescueLink included with this new AED there may be features described in this manual that cannot be edited. The software in most cases will give an error message when incompatibilities occur.

[1] Cummins, R., ed., Advanced Cardiac Life Support; AHA (1994): Ch. 4.

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SYMBOL DESCRIPTIONS

The following symbols may appear in this manual, on the AED, or on its optional components. Some of the symbols represent standards and compliances associated with the AED and its use.

Dangerous Voltage: The defibrillator output has high voltage and can present a shock hazard. Please read and understand all safety alerts in this manual before attempting to operate the AED.

Attention!: Identifies important information in this manual, on the AED, or on its component parts regarding the safe and proper use of the AED.

Defibrillator Proof Type BF Equipment: The AED, when connected to the patient's chest by the pads, can withstand the effects of an externally applied defibrillation shock.

CE Mark: This equipment conforms to essential requirements of the Medical Device Directive 93/42/EEC.

IP24 The AED is protected against the effects of splashing water in accordance with IEC 60529.

Classified by ETL Semko with respect to electric shock, fire and mechanical hazards only in accordance with UL 60601-1, CAN/CSA C22.2 No.601.1-M90, EN60601-1 and EN60601-2-4. Conforms to UL Standard UL60601-1. Certified to CAN/CSA Standard C22.2 No. 601.1-M90.

International symbol for ON. Open the lid to turn on the AED.

Open the lid to turn ON the AED.

Indicates the AED battery status. The illuminated areas indicate the remaining battery capacity.

Check pads. The pads are missing, not connected or have compromised functionality.

Indicates AED requires maintenance by authorized service personnel.

When the **SHOCK** indicator is lit, push this button to deliver a defibrillation shock.

When the **CONTINUE** indicator is lit, push this button to clear the internal memory to allow storage of new rescue data in the AED. (Only for models not equipped with Multiple Rescue software)

A red indicator with a BLACK X means the Responder AED requires operator attention or maintenance, and is not RescueReady. This symbol will be referred to as **RED** in the remainder of this manual.

A green indicator without a BLACK X means the Responder AED is RescueReady. This symbol will be referred to as **GREEN** in the remainder of this manual.

Use pads by this date; install battery by this date.

exp. date Expiration Date. Replace by this date.

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Date of manufacture.

Date of factory recertification (R)

Latex Free.

Disposable. Single patient use only.

Tear here to open.

Do not recharge battery.

Position of pads on the chest of patient.

Dispose of properly in accordance with all state, province, and country regulations.

Do not incinerate or expose to open flame.

Explosion Hazard: Do not use in the presence of a flammable gas, including Concentrated oxygen.

Upper and lower temperature limits.

Device Model Number

Serial Number

Lot Number

Revision

Lithium Sulfur Dioxide

Serial Communication Port

Additional information is provided in the AED Operator's Manual.

Points to important information regarding the use of the AED.

Lift Here

Symbol for the marking of electrical and electronic equipment that must be recycled.

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Manufacturer

Authorized European Representative

Fragile; handle with care

Keep away from rain. (Keep dry)

This way up

Stacking limit by number

General symbol for recovery/recyclable

Humidity Limitations

Atmospheric Pressure Limitations

In November 2005, the American Heart Association (AHA) and European Resuscitation Council (ERC) released new guidelines for CPR and defibrillation. This symbol indicates that the AED contains the new AHA/ERC guidelines for CPR and defibrillation.

SAFETY AND PERFORMANCE STANDARDS

AED MODELS 2019198

The AED has been designed and manufactured to conform to the highest standards of safety and performance including electromagnetic compatibility (EMC). The Responder AED Model 2019198 and pads conform to the applicable requirements of the following:

CE
CE Marked by BSI 0086 per the Medical Device Directive 93/42/EEC of European Union

ETL
Classified by ETL Semko with respect to electric shock, fire and mechanical hazards only in accordance with UL 60601-1, CAN/CSA C22.2 No.601.1-M90, EN60601-1 and EN60601-2-4. Conforms to UL Standard UL60601-1. Certified to CAN/CSA Standard C22.2 No. 601.1-M90.

Electrical, Construction, Safety and Performance
IEC 60601-1 (1998), Amendments 1 (1991) & 2 (1995)
IEC 60601-2-4 (2002)
IEC 60601-1-4 (2000)
ANSI/AAMI DF-39 (1993)

Electromagnetic Compatibility (EMC)
IEC 60601-1-2 (2001)
IEC 60601-2-4 Section 36
ANSI/AAMI DF-39(1993) Section 3.3.21

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OPERATOR TRAINING REQUIREMENTS

Persons authorized to operate the AED must have all of the following minimum training.

- Defibrillation training and other training as required by state, province, or country regulations.
- Training on operation and use of the AED.
- Additional training as required by the physician or Medical Director.
- A thorough understanding of the procedures in this manual.

Note: Keep valid certificates of training and certification as required by state, province, or country regulations.

Persons authorized to operate AEDs must have training in accordance to state, province or country regulations.

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FOR YOUR NOTES:

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SECTION 2: GETTING STARTED

OVERVIEW

This section presents information on unpacking and setting up the AED

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UNPACKING AND INSPECTING

Every attempt is made to ensure your order is accurate and complete. However, to be sure that your order is correct, verify the contents of the box against your packing slip.

ENVIRONMENTAL OPERATING AND STANDBY CONDITIONS

See Section 6 – Technical Data, Parameters, Environmental Operation and Standby Conditions.

CAUTION: Temperature/Humidity/Pressure Extremes
Exposing the AED to extreme environmental conditions outside of its operating parameters may compromise the ability of the AED to function properly. The RescueReady® daily self test verifies the impact of extreme environmental conditions on the AED by checking temperature, humidity and pressure; if the daily self test determines environmental conditions outside of the AED's operating parameters for 5 consecutive days, a "SERVICE REQUIRED" alert will be issued to prompt the user to move the AED to environmental conditions within the acceptable operating parameters at once. See Section 6 – Technical Data, Parameters, Operation and Standby Conditions.

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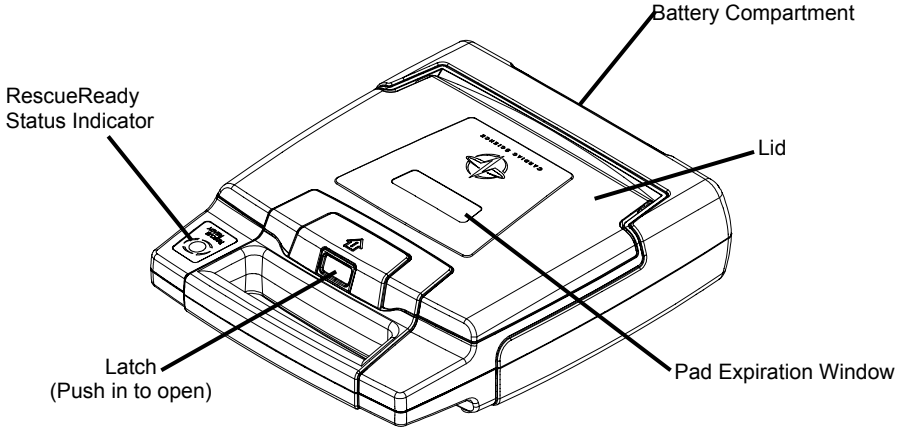
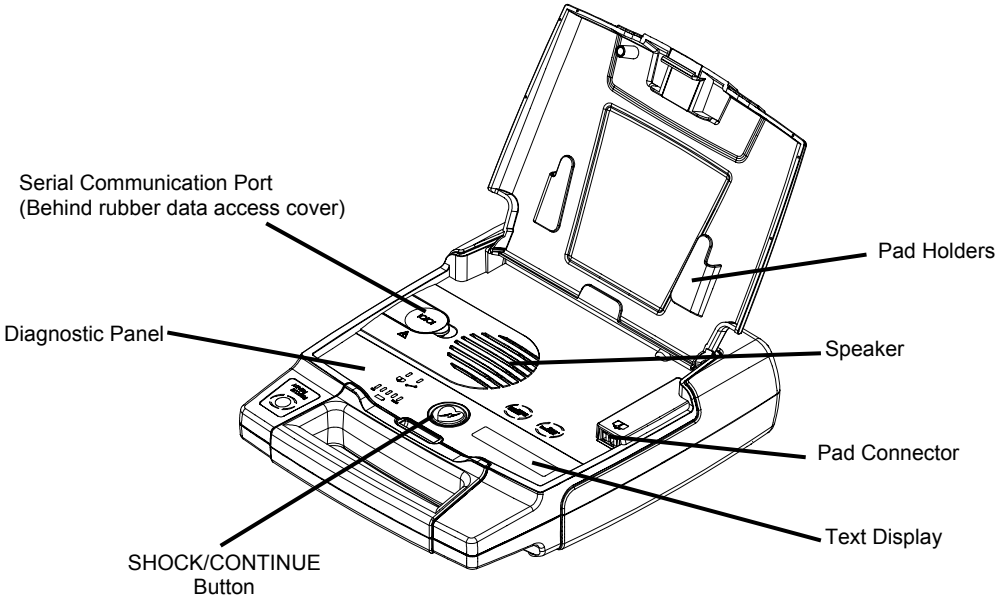
AED PARTS

The following drawings show the AED parts and their locations.





THE AED HAS THREE MODES:

Operating Mode: Defined as having the battery installed and the lid open. This is the mode the AED would be in during an actual rescue situation.

Standby Mode: When the battery is installed, but the lid is closed. In this mode the AED is not being used in a rescue. The device will conduct its routine self-tests to ensure proper operation.

Storage Mode: When the battery is removed, such as during shipping or transport. With the battery removed, the AED is unable to perform self-tests or rescues.

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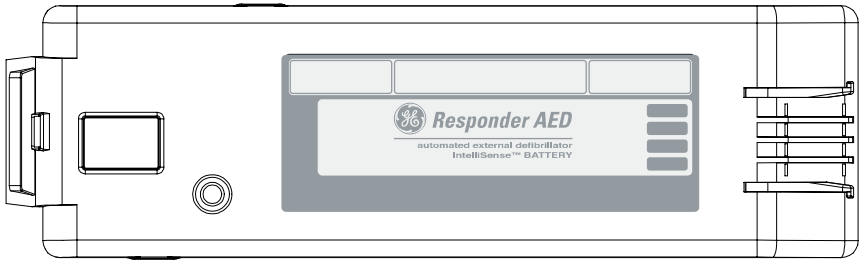
INTELLISENSE® BATTERY



INSTALLATION

- Insert battery as shown.
- Push firmly to snap into place.
- Open the lid for 5 seconds.
- The Status Indicator turns GREEN

ABOUT THE INTELLISENSE® BATTERY

- When the last battery indicator (LED) is red, the battery is low. Replace the battery right away.
- A new battery typically takes 10 seconds to charge the AED to maximum energy.
- AED batteries will provide up to 290 shocks
- Output voltage: 12VDC (max)
- Batteries are non-rechargeable
- Lithium contents: 9.2g (max)
- Check local regulations for disposal information

MODEL	TYPICAL SHOCKS
2019437(9142) Lithium	Up to 290

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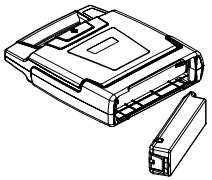
BATTERY SHELF LIFE

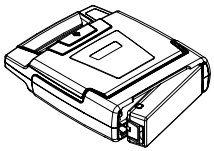
The Responder AED batteries have a shelf life of five years. Shelf life is defined as the length of time a battery can be stored, prior to installation into AED, without degrading its performance.

Note: Storing the battery outside its specific range (0-50°C)(30-122°F) will decrease battery life.

BATTERY INSTALLATION



1. With the label on the battery facing the AED battery compartment, insert the battery as shown in the drawing.



2. Push the latched end of the battery firmly into the AED, as shown in the drawing, until the battery snaps into place. The exposed side of the battery should be flush with the outside of the AED case.

3. Open the lid for 5 seconds to initiate self-test. If the battery is installed properly, the STATUS INDICATOR will turn GREEN. Close the lid.

WARNING: Battery is Not Rechargeable
Do not attempt to recharge the battery. Any attempt to recharge the battery may result in an explosion or fire hazard.

CAUTION: Lithium Sulfur Dioxide Battery
Pressurized contents: Never recharge, short circuit, puncture, deform, or expose to temperatures above 65°C (149°F). Remove the battery when discharged.

CAUTION: Battery Disposal
Recycle or dispose of the lithium battery in accordance with all federal, state and local laws. To avoid fire and explosion hazard, do not burn or incinerate the battery.

CAUTION: Use only General Electric Approved Equipment
Using batteries, pads, cables, or optional equipment other than those approved by General Electric may cause the Responder AED to function improperly during a rescue.

CAUTION: Possible Improper AED Performance
Using pads that are damaged or expired may result in improper AED performance

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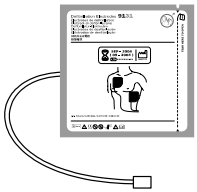
PADS



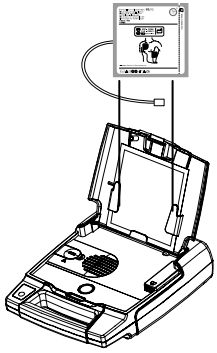
The defibrillation pads come in a ready-to-use, sealed package containing one pair of self-adhesive pads with an attached cable and connector. The pads are disposable and should be discarded after each rescue. The pads have a limited shelf life and shall not be used beyond the expiration date. Keep a fresh, unopened pair of pads plugged into the AED at all times. Refer to the pads package label for operation temperatures.

On the Responder AED, an audible and visual alert will indicate after the self-test if the pads are missing, unplugged or damaged.

CAUTION: Possible Improper AED Performance

Using pads that are damaged or expired may result in improper AED performance.

PAD INSTALLATION



1. Open the lid of the AED.
2. Place the pads package into the lid so that the expiration label is visible through the clear window on the lid. The expiration date of the pads will then be readable without opening the lid of the AED.
3. Match the color of the connectors (red to red), then plug the pad connector into the AED case as shown in the drawing.
4. Tuck the excess cable length in the bottom holder as shown in the drawing. With the pad package completely secured to the AED lid, close the lid.
5. Make sure the expiration date is visible through the clear window of the lid.
   Make sure that the **STATUS INDICATOR** is **GREEN**.

CAUTION: Use only Approved Equipment
Using batteries, pads, cables, or optional equipment other than those approved by General Electric may cause the AED to function improperly during a rescue.

CAUTION: Possible Improper AED Performance
Using pads that are damaged or expired may result in improper AED performance.

DIRECTIONS FOR USE:

1. Do NOT open until ready to use, short term use only.
2. Ensure the skin site is clean and dry.
3. Separate one pad from liner.
4. Place one pad on skin in either position.
5. Peel and place remaining pad.

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AED INDICATORS

The following indicators are located on the AED.

RESCUEREADY® STATUS INDICATOR

The **STATUS INDICATOR** is located on the Responder AED handle. When this indicator is **GREEN**, the device is RescueReady. This means the Responder AED self-tests have verified the following:

- Battery has an adequate charge.
- Pads are properly connected to the Responder AED and in working order.
- Integrity of the internal circuitry is good.

When the **STATUS INDICATOR** is **RED**, maintenance is required.

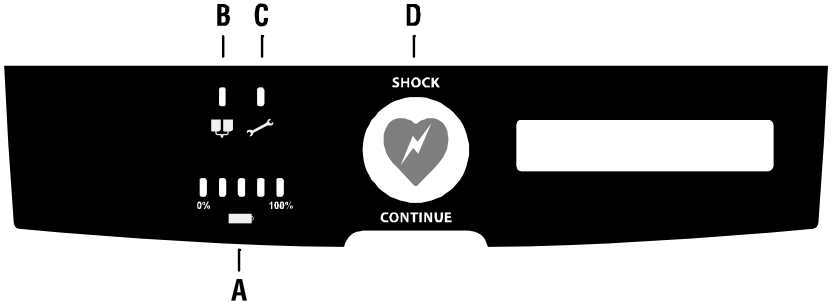
Note: When Status Indicator is RED or Service Indicator is illuminated, device cannot be used to perform a rescue.

AUDIBLE MAINTENANCE INDICATOR

When the daily, weekly or monthly self-test determines service is required, an audible beep is sounded every 30 seconds until the lid is opened or the battery power is depleted. Opening and closing the lid may deactivate the beep. If the error is not corrected by the next automatic self-test, the beep will be reactivated.

DIAGNOSTIC PANEL

A **SMARTGAUGE BATTERY** Indicator
B **PADS** Indicator
C **SERVICE** Indicator
D **SHOCK/CONTINUE** Button



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SMARTGAUGE™ BATTERY STATUS INDICATOR

The SmartGauge Battery Status Indicator has five (5) LEDs, four (4) green and one (1) red. The right four green LEDs display the remaining capacity of the battery much like a fuel gauge. With use, the green LEDs gradually go out, from right to left, as battery capacity decreases.
When the green LEDs go out and the red LED lights up, replace the battery.

Note: When the red LED initially lights up – upon lid opening or at any time during a rescue – a "Battery Low" prompt will be issued at once. However, the AED is capable of delivering at least 9 more defibrillation shocks after the first "Battery Low" prompt is issued.

When the AED battery cannot deliver any more shocks, the AED display will show "BATTERY LOW", the STATUS INDICATOR will be RED and the device will "beep" every 30 seconds.. To continue the rescue, leave the lid open, remove the battery, and replace with a fresh battery. If battery replacement takes longer than 60 seconds, the first rescue will be terminated and a second rescue will begin upon opening the lid.

PADS INDICATOR

The **PADS** LED lights up when the pads are:

- Not properly connected to the AED
- Not within operational specifications (cold, dried, damaged).
- Disconnected from the patient during a rescue.

SERVICE INDICATOR

The **SERVICE** LED lights up when the AED requires maintenance that can only be performed by qualified service personnel.

Note: When Status Indicator is RED or Service Indicator is illuminated, device cannot be used to perform a rescue.

SHOCK/CONTINUE BUTTON

- The AED has one button called the **SHOCK/CONTINUE** button. This button is located on the diagnostic panel.

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SHOCK INDICATOR

The word **SHOCK** and the shock button indicator LED will illuminate red when the AED is ready to deliver a defibrillation shock to the patient.

CONTINUE INDICATOR

The word **CONTINUE** will illuminate yellow and the continue button indicator LED will illuminate red when the previous rescue data has not been cleared from the internal memory.

***Note**:* Only for models not equipped with Multiple Rescue software

TEXT DISPLAY

The text display has 2 lines of text. The text display provides the operator with information regarding system initialization, text prompts and data during a rescue, and diagnostics.

System initialization occurs when the lid is first opened. The text display shows the operator the identifiers for the internal code, voice prompts and text prompts versions. The text display also shows the current date and time.

During a rescue, the text display shows the number of shocks delivered and the elapsed time from the beginning of the rescue (when the lid was first opened). During CPR, a countdown timer will be displayed. The text version of the voice prompts will also be displayed.

Note: There is a 3 second delay between the time the AED lid is opened and the start of the rescue. This 3 second delay is not included in the elapsed rescue time.

SETTING THE AED INTERNAL CLOCK

The internal clock is preset at Central Standard Time and should be reset to the correct date and local time. The AED will automatically adjust itself for daylight savings time. This feature can be turned off using the ServiceLink software. To set the clock, you will need a PC with Windows 95 or later operating system, RescueLink software installed and a serial communications cable.

To set the clock settings:

- Open the lid and remove pads from the pads socket.
- Connect the AED to the PC using the serial communications cable.
- Ensure that the PC is set at the correct local time and date.
- Run the RescueLink software on the PC.
- Verify that the voice prompt states “Communications Mode”.
- Click Communications on the main menu. Select AED Date and Time.
- Click on the Get button to review the current time in the AED.
- If the time and date is incorrect, click Set to set new time and date. The AED date and time will automatically be updated to the PC’s time and date.
- Reinstall pads per instructions on page 15.
- Disconnect the serial communications cable and close the lid.

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VOICE PROMPTS AND TEXT DISPLAY

The voice prompts activate when the AED lid is opened and help guide the operator through the rescue. The Responder AED text display provides a visual display of most of the audible voice prompts.

The following table lists the voice and text prompts and a description of when the prompts are issued.

VOICE PROMPT	TEXT DISPLAY	SITUATION
"Tear Open Package and Remove Pads."	OPEN PACKAGE AND REMOVE PADS	When the lid is opened, this phrase is repeated twice to initiate the rescue sequence.
"Peel One Pad from Plastic Liner."	PEEL ONE PAD FROM PLASTIC LINER	Repeats until one pad is peeled off of the liner.
"Place One Pad on Bare Upper Chest."	PLACE ONE PAD ON BARE UPPER CHEST	Repeat twice while one pad is placed.
"Peel Second Pad and Place on Bare Lower Chest as Shown."	PEEL SECOND PAD PLACE ON LOWER CHEST	Repeats until both pads are placed on the patient.
"Do Not Touch Patient! Analyzing Rhythm."	DO NOT TOUCH PATIENT ANALYZING RHYTHM	When the AED is analyzing the cardiac rhythm of the patient.
"Shock Advised."	SHOCK ADVISED	When the AED is preparing to deliver a defibrillation shock.
"Charging."	CHARGING	Repeated while AED is charging.
"Stand Clear! Push Flashing Button to Deliver Shock."	STAND CLEAR PUSH BUTTON TO SHOCK	After the AED is fully charged and ready to deliver the defibrillation shock. The RED Shock indicator flashes and the phrase repeats for 30 seconds or until the Shock button is pushed.

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(VOICE PROMPT AND TEXT DISPLAY CONTINUED)

VOICE PROMPT	TEXT DISPLAY	SITUATION
Shock Delivered.	SHOCK DELIVERED	After the AED delivers a defibrillation shock
"It is now safe to touch the patient."	IT IS NOW SAFE TO TOUCH THE PATIENT.	Advises the rescuer when it is safe to touch the patient.
Start CPR	START CPR	After the AED delivers a defibrillation shock After the AED detects a non-shockable rhythm.
Give 30 compressions *Then Give Two Breaths*	30 COMPRESSIONS 2 BREATHS	Perform CPR for 2 minutes.
"Check Pads"	CHECK PADS	Occurs when patient impedance is too low or too high.
"Battery Low"	BATTERY LOW	Occurs once when the battery voltage becomes low, although a rescue can continue for approximately 9 more shocks. When the battery is too low to do a rescue, the phrase repeats continuously. You must replace the battery before continuing with the rescue. If completely depleted, all AED activity will terminate.
"Analysis Interrupted. Stop Patient Motion."	ANALYSIS INTERRUPTED STOP PATIENT MOTION	When the AED detects ECG noise artifact, stop moving or touching the patient. Remove other electronic devices within a 5-meter radius.
"Open Lid to Continue Rescue"	OPEN LID TO CONTINUE RESCUE	When the lid is inadvertently closed during a rescue, this prompt will repeat for 15 seconds.
"Rhythm Changed. Shock Cancelled."	RHYTHM CHANGED. SHOCK CANCELLED	When the AED detects a change in rhythm – when the device is prepared to shock.

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(VOICE PROMPT AND TEXT DISPLAY CONTINUED)

VOICE PROMPT	TEXT DISPLAY	SITUATION
"Remove cable to continue rescue"	REMOVE CABLE	When a serial communication cable is connected to the AED during a rescue, the phrase repeats until the cable is disconnected.
"Communications Mode"	COMMUNICATIONS MODE	When the lid is open and the serial communication cable is plugged into the AED.
(Beep)	(NO TEXT)	"One Beep" occurs in 30-second intervals during CPR when enabled by Service using the ServiceLink software program, "Warble Beep" occurs when the AED requires maintenance.
"Continue CPR"	CONTINUE CPR	During CPR mode when enabled, or when a rescue is resumed in CPR mode after being interrupted by the lid closing.
"Service Required"	SERVICE REQUIRED	Occurs after the self-tests determine that the AED is not functioning properly. The prompt "*SERVICE REQUIRED*" will be heard when the lid is opened. The red **SERVICE** indicator will illuminate and "*SERVICE REQUIRED*" will repeat until you close the lid. After closing the lid, an alarm beep will be heard until the battery is removed or becomes completely depleted.

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SECTION 3: PERFORMING A RESCUE

OVERVIEW

The AED is designed for ease of data management and review. The data stored in internal memory can be displayed on the PC screen using the RescueLink software.

TOPIC	PAGE #
HOW TO PERFORM A RESCUE	23
WARNINGS	25
AFTER A RESCUE ATTEMPT	26

HOW TO PERFORM A RESCUE

STEP 1: ASSESS

CALL EMERGENCY MEDICAL SERVICES

The patient is unresponsive.

AND

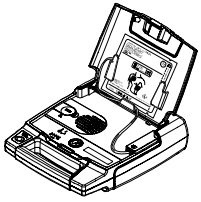
The patient is not breathing.

CALL EMERGENCY MEDICAL SERVICES

Perform CPR until AED is attached to patient.

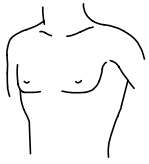
When the patient is under 8 years of age or weighs less than 55lbs (25kg), the AED should be used with the Pediatric Attenuated Defibrillation Electrode Pads. Therapy should not be delayed to determine the patient's exact age or weight. See the directions for use accompanying pediatric electrode pads for procedure on changing adult electrode pads to pediatric and to change energy protocols.

STEP 2: PREPARE



- Open the AED lid.

Note: When Status Indicator is RED or Service Indicator is illuminated, device cannot be used to perform a rescue.



- Remove clothing from the patient's chest.
- Ensure the skin site is clean and dry.
- Dry the patient's chest and shave excessive hair if necessary.

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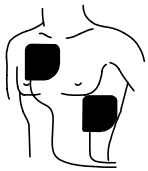
STEP 3: PLACE PADS

- Tear open pad package and remove pads.
- Peel one pad from plastic liner.



- Place one pad on bare upper chest.
- Peel second pad and place on bare lower chest as shown.

STEP 4: ANALYZE AND SHOCK DELIVERY

The voice and text prompts will guide you through.

- *"DO NOT TOUCH PATIENT! ANALYZING RHYTHM."*

If a shockable rhythm is detected, follow these instructions:

- *"SHOCK ADVISED."*
- *"CHARGING"*
- *"STAND CLEAR! PUSH FLASHING BUTTON TO DELIVER SHOCK."*

If the patient's rhythm changes to a non-shockable rhythm before the actual shock is delivered, the AED will advise that the rhythm has changed and issue the prompt "*RHYTHM CHANGED, SHOCK CANCELLED*." The AED will override the charge and prompt, "Start CPR".

STEP 5: CPR MODE

- When instructed, start CPR
- Give 30 compressions followed by 2 breaths.

At the end of the CPR period, the voice prompts will direct you to repeat steps 4 and 5 if required.

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WARNINGS

The following cautions must be observed to prevent problems during the rescue.

DANGER: Fire and Explosion Hazard
Do not use in the presence of flammable gases (including concentrated oxygen) to avoid possible explosion or fire hazard.

WARNING: Shock Hazard
Defibrillation shock current flowing through unwanted pathways is potentially a serious electrical shock hazard. To avoid this hazard during defibrillation abide by all of the following:

- Do not touch the patient, unless performance of CPR is indicated
- Do not touch metal objects in contact with the patient
- Keep defibrillation pads clear of other pads or metal parts in contact with patient
- Disconnect all non-defibrillator proof equipment from the patient before defibrillation

WARNING: Shock and Possible Equipment Damage
Disconnect all non-defibrillator proof equipment from the patient before defibrillation to prevent electrical shock and potential damage to the equipment.

WARNING: Electric Shock and Fire Hazard
Do not connect any telephones or unauthorized connectors to the socket on this equipment.

CAUTION: Use only Approved Equipment
Using batteries, pads, cables, or optional equipment other than those approved by General Electric may cause the Responder AED to function improperly during a rescue.

CAUTION: Possible Improper AED Performance
Using pads that are damaged or expired may result in improper AED performance.

CAUTION: Serial Communication Cable
The AED will not function during a rescue when the serial communication cable is connected to its serial port. When the serial communication cable is connected to the AED during a rescue, the prompt “Remove cable to continue rescue” will be heard until you remove the serial communication cable from the AED.

CAUTION: Possible Radio Frequency (RF) Susceptibility
RF susceptibility from cellular phones, CB radios and FM 2-way radio may cause incorrect rhythm recognition and subsequent shock advisory. When attempting a rescue using the AED, do not operate wireless radiotelephones within 1 meter (3.3 feet) of the AED – turn power OFF to the radiotelephone and other like equipment near the incident.

CAUTION: Possible Interference with Implanted Pacemaker
Therapy should not be delayed for patients with implanted pacemakers and a defibrillation attempt should be made if the patient is unconscious and not breathing. The AED has pacemaker detection and rejection, however with some pacemakers the AED may not advise a defibrillation shock.

Placing Pads:

- Do not place the pads directly over an implanted device.
- Place the pad at least on inch from any implanted device.

CAUTION: Moving the Patient During a Rescue
During a rescue attempt, excessive jostling or moving of the patient may cause AEDs to improperly analyze the patient’s cardiac rhythm. Stop all motion or vibration before attempting a rescue.

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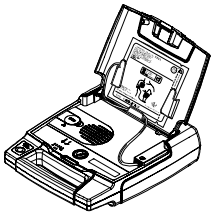
AFTER A RESCUE ATTEMPT



After transferring the patient to Advanced Life Support personnel, prepare the AED for the next rescue:

1. Retrieve the rescue data stored in the internal memory of the AED. Refer to Section 4 of this manual.
2. Connect a new pair of pads to the AED.
3. Check Battery. Close the AED lid.

4. Verify the **STATUS INDICATOR** on the AED handle is **GREEN**.

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SECTION 4: DATA MANAGEMENT

OVERVIEW

The AED is designed for ease of data management and review. The data stored in internal memory can be displayed on the PC screen using the RescueLink software.

TOPIC	PAGE #
RECORDING THE RESCUE DATA	27
REVIEW THE RESCUE DATA	27
RESCUELINK OVERVIEW	28
RESCUELINK INSTALLATION INSTRUCTIONS	29
MULTIPLE RESCUE FUNCTIONALITY	29

RECORDING THE RESCUE DATA

RECORDING DATA IN INTERNAL MEMORY

The AED automatically stores up to 60 minutes of the latest rescue data.

REVIEWING THE RESCUE DATA

RETRIEVING DATA FROM MEMORY

1. Open the AED lid.
2. Connect the serial cable to the PC and to the AED's serial port under the rubber data access cover. The voice prompt will say "*Communications Mode."*
3. Run the RescueLink software program.
4. Select **COMMUNICATIONS**, then **GET RESCUE DATA** on the RescueLink software program.
5. Select Internal Memory of AED then select OK.
6. Once the data is saved, close the AED and remove the serial cable.

WARNING: Electric Shock and Fire Hazard
Do not connect any telephones or unauthorized connectors to the socket on this equipment.

CAUTION: Serial Communication Cable
The serial communication cable is only for use with the AED; it is not to be used with a telephone.

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RESCUELINK OVERVIEW

RescueLink® software application is used for transferring, viewing, and storing rescue data recorded by an automated external defibrillator.

Note: Rescue data managed by RescueLink is for archival purposes only. RescueLink does not attempt to interpret medical information and is not a medical device.
RescueLink allows you to manage rescue data retrieved from the AED by transferring rescue data from the AED to a computer.

The computer may then be used to:
• View, print and store rescue data
• Display and set the AED date and time
• Clear rescue data from the AED

RescueLink is programmed with on-line Help. Help may be accessed by selecting *Help, Search for Help on….* from the menu bar.

RESCUELINK SOFTWARE PC REQUIREMENTS

The following is a list of minimum requirements need to install the RescueLink software.

TYPE	SPECIFIC
Processor	486SX - 66MHz
RAM	16 Megabytes
Hard Drive	20 Megabytes free space
Operating System	Windows 95 Windows 98 Windows 2000 Windows XP
Communications Port	COM 1
Printer Port	LPT1 or network printer
PCMCIA card reader	Type I or Type II PCMCIA Card Reader
Sound	Sound Blaster Compatible Audio Card with Stereo Speakers
Screen Area	600 X 800 pixels
Mouse	Windows compatible
Printer	Windows compatible
Keyboard	Windows compatible
CD-ROM	Windows compatible

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RESCUELINK INSTALLATION INSTRUCTIONS

Note: You will need administrator privileges to install the RescueLink software application.

To install RescueLink, follow these steps:

1. Verify your computer meets the minimum requirements as defined in *RescueLink Software PC Requirements* section of this manual.
2. Quit all programs and insert the RescueLink CD into your CD ROM drive.
3. The installation routine will start automatically after inserting the CD.
   If the installation routine does not start automatically, run the setup.exe file from the CD.
4. Choose your language and Click OK. The program will automatically default to the operating system language on your computer.
5. The installation program will guide you through the installation process.
6. After successful installation, you will be able to run RescueLink by:
   a. Selecting *Start, All Programs*, Cardiac Science Corp, RescueLink; or
   b. Clicking on the RescueLink icon on your computer's desktop
   c. Simultaneously selecting Ctrl +Alt +R on your keyboard

MULTIPLE RESCUE FUNCTIONALITY

The AED can store up to 60 minutes of ECG monitoring time in the AED's internal memory. Multiple rescues can be stored in the internal memory, allowing the rescuer to administer additional rescues without downloading the data to a PC. Should the internal memory become full, the AED will purge rescues as needed, beginning with the oldest rescue.

When downloading data, RescueLink will enable the user to select which rescue to download. See the RescueLink application HELP files for more information.

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SECTION 5: MAINTENANCE & TROUBLESHOOTING

OVERVIEW

This section presents information about the AED diagnostics self-tests, maintenance, and service indications.

TOPIC	PAGE #
SELF TESTS	31
INDICATOR TROUBLESHOOTING TABLE	32
SCHEDULED MAINTENANCE	32
AUTHORIZED REPAIR SERVICE	34
FREQUENTLY ASKED QUESTIONS	35

SELF-TESTS

The AED has a comprehensive self-test system that automatically tests the electronics, battery, pads, and high voltage circuitry. Self-tests are also activated every time you open and close the AED lid.

These self-tests eliminate the need for in depth periodic / annual maintenance testing. The comprehensive self-tests insure that the Responder AED is RescueReady®, with minimal user involvement and maintenance costs. Once a month during the daily self-tests, the AED performs a full charge of the capacitors. During this test the AED monitors the charge time, voltage level and proper discharge function. When the Responder AED requires maintenance, audible and/or visual indicators are activated. By monitoring the visual and audible indicators, the user can be assured that the Responder AED is ready to conduct a rescue.

When performing the self-tests, the AED completes the following steps automatically.

- Turns itself ON, and the **STATUS INDICATOR** changes to **RED**.
- Performs the self-test.
- If successful, the **STATUS INDICATOR** reverts to **GREEN**.
- Turns itself OFF if the lid is closed.

There are three types of automatic self-tests. The Daily Self-Test checks the battery, pads, and the electronic components. The Weekly Self-Test completes a partial charge of the high voltage electronics current in addition to the items tested in the Daily Self-Test. During the Monthly Self-Test, the high voltage electronics are charged to full energy.

Self-tests will be initiated upon opening the lid and again upon closing the lid. If the self-test detects an error, the **STATUS INDICATOR** will remain **RED**. Upon closing the lid, an audible alert will be issued. The Diagnostic Panel under the lid will indicate the source of the problem according to the Indicator Troubleshooting Guide Table on the next page.

CAUTION: Temperature/Humidity/Pressure Extremes
Exposing the AED to extreme environmental conditions outside of its operating parameters may compromise the ability of the AED to function properly. The RescueReady® daily self test verifies the impact of extreme environmental conditions on the AED by checking temperature, humidity and pressure; if the daily self test determines environmental conditions outside of the AED's operating parameters for 5 consecutive days, the "SERVICE REQUIRED" alarm will sound to alert the user to move the AED to environmental conditions within the acceptable operating parameters at once. See Section 6 – Technical Data, Parameters, Operation and Standby Conditions.

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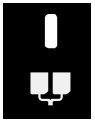
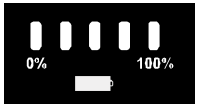
INDICATOR TROUBLESHOOTING TABLE

The following is a troubleshooting table for the AED indicators.

VIEW	SYMPTOM	SOLUTION
	Red **SERVICE** indicator (LED) is lit.	Maintenance by authorized service personnel is required. Call Customer Service or your local distributor.
	Red **PADS** indicator (LED) is lit.	Connect the pads or replace with a new pair.
	The **LAST BATTERY** indicator (LED) is red.	The battery is low. Replace with a new battery.
	STATUS INDICATOR is **RED**, and no other indicators on the diagnostic panel are lit.	The battery power is completely depleted. Replace with a new battery. If **STATUS INDICATOR** remains **RED**, refer the Responder AED to maintenance. Call Customer Service or your local distributor.

SCHEDULED MAINTENANCE

DAILY MAINTENANCE

Check the **STATUS INDICATOR** to ensure that it is **GREEN**. When the indicator is **GREEN**, the Responder AED is ready for a rescue. If the indicator is **RED**, refer to the Troubleshooting Table in this chapter.

MONTHLY MAINTENANCE

1. Open the AED lid.
2. Wait for the AED to indicate status
3. Observe the change of the **STATUS INDICATOR** to **RED**. After less than 5 seconds, verify that the **STATUS INDICATOR** returns to **GREEN**.
4. Observe the expiration date on the pads.
5. Listen for the voice prompts.
6. Close the lid and confirm that **STATUS INDICATOR** remains **GREEN**.

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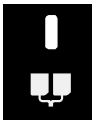
ANNUAL MAINTENANCE

Perform the following tests annually to confirm that the diagnostics are functioning properly and to verify the integrity of the case.



Check the Integrity of the Pads and Circuitry

1. Open the AED lid.
2. Remove the pads.
3. Close the lid.
4. Confirm that the **STATUS INDICATOR** turns **RED**.
5. Open the lid and confirm that the **PAD** indicator is lit.
6. Reconnect the pads and close the lid.
7. Make sure the expiration date is visible through the clear window of the lid.
8. Check to make sure that the **STATUS INDICATOR** is **GREEN**.
9. Open the lid and confirm that no diagnostic indicators are lit.
10. Check the expiration date of the pads; if expired, replace them.
11. Check the pads' packaging integrity.
12. Close the lid.

Check the Integrity of the Service Indicator (LED) and Circuitry

1. Immediately after opening the AED lid, press and hold the **SHOCK** button and confirm that the **SERVICE** LED is lit.
2. Release the **SHOCK** button.
3. Close the lid.
4. Verify that the **STATUS INDICATOR** remains RED.
5. Open the lid and confirm that no diagnostic indicators are lit.
6. Close the lid.
7. Verify the **STATUS INDICATOR** turns GREEN.

Check the Integrity of the Case

Examine the molded case of the AED for any visible signs of stress. If the case shows signs of stress, contact Customer Service or your local distributor.

Cleaning the AED Case

Gently clean the surface of the AED case with a damp sponge or with a cloth and mild soap.

CAUTION: Case Cleaning Solutions
When disinfecting the case, use a non-oxidizing disinfectant, such as ammonium salts or a glutaraldehyde based cleaning solution, to avoid damage to the metal connectors.

No periodic safety analysis tests referred to by the IEC 60601-1 international standard are required.

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AUTHORIZED REPAIR SERVICE

The AED has no user-serviceable internal components. Try to resolve any maintenance issues with the AED by using the Troubleshooting Table presented in this chapter. If you are unable to resolve the problem, contact Customer Service.

WARNING: Shock Hazard
Do not disassemble the AED! Failure to observe this warning can result in personal injury or death. Refer maintenance issues to authorized service personnel.

Note: The warranty will be void upon unauthorized disassembly or service of the AED.

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FREQUENTLY ASKED QUESTIONS

QUESTIONS AND ANSWERS

1. Q: *Can I give CPR while the AED is analyzing?*
   A: No. As with all AEDs, the operator should stop CPR compressions during the analysis phase.

2. Q: *Can I transport the victim while the AED is analyzing?*
   A: No. Vehicle motion may cause noise artifacts that could interfere with proper cardiac rhythm analysis. Stop the vehicle when cardiac rhythm analysis is necessary.

3. Q: *Do I need to prepare the chest prior to pad application?*
   A: Special preparation is not usually necessary. The chest should be as clean, dry, and as oil free as possible. In some cases, the chest may need to be shaved. Follow your Medical Director's instruction.

4. Q: *What happens if the battery is low when I begin a rescue?*
   A: When the **BATTERY INDICATOR** is **RED**, the AED issues a "*Battery Low*" prompt once; however, the AED is still capable of delivering approximately 9 more defibrillation shocks.

   When the AED is not capable of delivering any more shocks, it "beeps" once every 30 seconds.. To continue the rescue attempt, leave the lid open and replace the battery. When the battery replacement takes longer than 60 seconds, the first rescue is terminated and the AED will begin to record the events from then on as a separate rescue.

5. Q: *How do I set the AED internal clock?*
   A: Set the clock by using the RescueLink Software Program and a PC. See Setting the AED Internal Clock in Chapter 3.

6. Q: *What happens if I close the lid in the middle of a rescue attempt?*
   A: If you close the lid during a rescue, you must re-open the lid within 15 seconds to continue the rescue. You will hear the prompt, "*Open lid to continue Rescue*." If the lid remains closed for more than 15 seconds, a new rescue will initiate when the lid is reopened.

   Note: If the lid is closed during a rescue while the pads are connected to the patient, the **STATUS INDICATOR** may turn **RED**. When the lid is reopened, however, the rescue may be continued even though the **STATUS INDICATOR** remains **RED**.

7. Q: *My AED is sounding an audible alert. Why? How do I stop it?*
   A: The audible alert indicates that the self-test detected a need for maintenance or corrective action. Determine the maintenance required by using the Troubleshooting Table in this chapter. Opening and closing the lid may turn OFF the audible alert until the next self-test. However, the **STATUS INDICATOR** will remain **RED**.

8. Q: *The AED did not sound an audible alert when I removed the pads and closed the lid. Why?*
   A: The lid-closed pad self-test only activates the **STATUS INDICATOR**. The AED allows time for replacement of the pads – as removing pads is a normal procedure after a rescue - or a battery during the post rescue procedure, however, an audible maintenance indicator will be triggered after the next Daily Self-Test.

9. Q: *What can I do to keep the AED warm when a rescue is in an isolated area and at subzero temperatures?*
   A: When travel to a rescue involves exposing the AED to extremely cold temperatures for an extended period of time, keep the pads and the battery warm.

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SECTION 6: TECHNICAL DATA

OVERVIEW

This section presents technical data about the AED.

TOPIC	PAGE #
PARAMETERS	37
RHYTHMX AED ECG ANALYSIS ALGORHITHM	40
STAR BIPHASIC WAVEFORM	42
STAR BIPHASIC ENERGY PROTOCOLS FOR RESPONDER AED	42
ELECTROMAGNETIC COMPATIBILITY REQUIREMENTS	44

PARAMETERS

OPERATION

Semi-Automatic (shock advisory)

AUDIBLE ALERTS

Voice Prompt
Maintenance Alert

VISIBLE INDICATORS

Status Indicator
Battery Status Indicator
Service Indicator
Pads Indicator
Text Display

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RESCUE DATA STORAGE

Storage	Capacity
Internal	60 minutes ECG data with event annotation

DIMENSIONS

Measurement	Dimension
Height	8 cm (3.3 in)
Width	27 cm (10.6 in)
Depth	31 cm (12.4 in)

WEIGHT

Model	Weight with Batteries and Pads
2019198	3.10 kg (6.6 lb)

ENVIRONMENTAL OPERATION AND STANDBY CONDITIONS

Atmosphere	Condition
Temperature	0°C to 50°C (32°F to 122°F)
Humidity	5% to 95% (non-condensing)
Pressure	57kPa (4,572m / +15,000ft) to 103kPa (-152m / -500ft)

SHIPMENT AND TRANSPORT ENVIRONMENTAL CONDITIONS (for up to 1 week)

Atmosphere	Condition
Temperature	-30°C to 65°C (-22°F to 149°F)
Humidity	5% to 95% (non-condensing)
Atmospheric Pressure	57kPa (4,527m / +15,000ft) to 103kPa (-152m / -500ft)

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PADS

- Self-adhesive, disposable defibrillation pads
- Minimum combined surface area: 228cm^2
- Extended length of lead wire: 1.3m

LITHIUM BATTERY SPECIFICATIONS

- **Output voltage: 12VDC (max)**
- Batteries are non-rechargeable
- Lithium contents: 9.2g (max)
- Check local regulations for disposal information

Model	Estimated Shelf Life	Warranty	Typical Shocks
2019437(9142) Lithium	5 Years	4 Years	Up to 290 shocks

The battery operating life depends on the type of battery, actual usage and environmental factors.

BATTERIES AND CAPACITOR CHARGE TIMES

A new battery typically takes 10 seconds to charge the AED to maximum energy.

A battery with reduced capacity causes the red LED light to initially turn ON and typically takes 13 seconds to charge a fully discharged AED to maximum energy.

The maximum time from “Power On” to “Ready to Shock” is 28 seconds for a new rescue.
The maximum time from “Analyze” to “Ready to Shock” is 22 seconds for a new rescue.

AED SELF-TEST SEQUENCE

Frequency of Self-Test	What is Tested?
Daily	Battery, pads, internal electronics, **SHOCK/CONTINUE** button, and software (no charge).
Weekly	Battery, pads, internal electronics, **SHOCK/CONTINUE** button, and software (partial charge).
Monthly (every 28 days)	Battery under load, pads, internal electronics, full-energy charge cycle, **SHOCK/CONTINUE** button, and software (full charge).
Open Lid (when lid is opened)	Battery, pads, internal electronics, **SHOCK/CONTINUE** button, and software.
Close Lid (when lid is closed)	Battery, pads, internal electronics, **SHOCK/CONTINUE** button, and software.

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RHYTHMX® AED ECG ANALYSIS ALGORHITHM

The RhythmX AED ECG analysis algorithm provides superior ECG detection capabilities, allowing it to be placed on patients at risk for sudden cardiac arrest. The features available with the AED include the following:

- Detection Rate
- Asystole Threshold
- Noise Detection
- Non-Committed Shock
- Synchronized Shock
- Pacemaker Pulse Rejection
- SVT Discriminators
- Supraventricular Tachycardia (SVT) Rate

DETECTION RATE

All ventricular fibrillation (VF) and ventricular tachycardia (VT) rhythms at or above this rate will be classified as shockable. All rhythms below this rate will be classified as non-shockable. This rate is configurable between 120 bpm (beats per minute) and 240 bpm. Service can change this rate using the ServiceLink software. The default Detection Rate is 160 bpm. The Responder AED detection rate is 160 bpm.

ASYSTOLE THRESHOLD

The Asystole baseline-to-peak threshold is set at 0.08 mV. ECG rhythms at or below 0.08 mV will be classified as Asystole and will not be shockable.

NOISE DETECTION

The AED will detect noise artifact in the ECG. Noise could be introduced by excessive moving of the patient or electronic noise from external sources like cellular and radiotelephones. When noise is detected, the AED will issue the prompt "*ANALYSIS INTERRUPTED. STOP PATIENT MOTION*" to warn the operator. The AED will then proceed to reanalyze the rhythm and continue with the rescue.

NON-COMMITTED SHOCK

After the AED advises a shock, it continues to monitor the patient ECG rhythm. If the patient's rhythm changes to a non-shockable rhythm before the actual shock is delivered, the AED will advise that the rhythm has changed and issue the prompt "*RHYTHM CHANGED. SHOCK CANCELLED*." The AED will override the charge and continue ECG analysis.

SYNCHRONIZED SHOCK

The AED is designed to synchronize shock delivery on the R-wave. The AED will automatically attempt to synchronize to the R-wave. If delivery cannot be synchronized within one second, a non-synchronized shock will be delivered.

PACEMAKER PULSE DETECTION

The AED contains pacemaker pulse detection circuitry to detect pulses from an implanted pacemaker.

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SVT (Supraventricular Tachycardia) DISCRIMINATORS

The Responder AED is supplied with the SVT Discriminator enabled and with the default setting "NO THERAPY FOR SVT". With the factory default setting of "NO THERAPY FOR SVT", the Responder AED will not shock an SVT rhythm.

SVT Discriminators are sophisticated filters that analyze the morphology of the ECG waveforms and distinguish VF/VT from SVT and Normal Sinus Rhythms (NSR). The SVT Discriminator will only be applied to rhythms that fall between the Detection Rate and the SVT Rate. The factory default setting for this feature is "NO THERAPY FOR SVT". Service can enable or disable this feature using the ServiceLink software.

SVT RATE

All rhythms with rates between the Detection Rate and SVT Rate will be screened through a number of SVT Discriminators to classify them into VF/VT or SVT. Rhythms classified as SVT between the two set rates are not shockable. All SVT rhythms above the rates will be classified as shockable. The SVT Rate must be greater than the Detection Rate and is selectable by Service between 160 and 300 bpm or, “NO THERAPY FOR SVT”. Service can enable or disable this feature using the ServiceLink software.

RESCUE PROTOCOL

The AED rescue protocol is consistent with the guidelines recommended by the American Heart Association (AHA)[1], European Resuscitation Council (ERC), and the International Liaison Committee on Resuscitation (ILCOR).

Upon detecting a shockable cardiac rhythm, the AED advises the operator to press the SHOCK button to deliver a shock and then advises the operator to start CPR.

Note: The standard CPR protocol of 120 seconds can be modified from 60 to 180 seconds in ServiceLink.

[1] Guidelines 2005 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care” American Heart Association; Circulation Vol 112, Issue 24 Suppl. Dec 13, 2005

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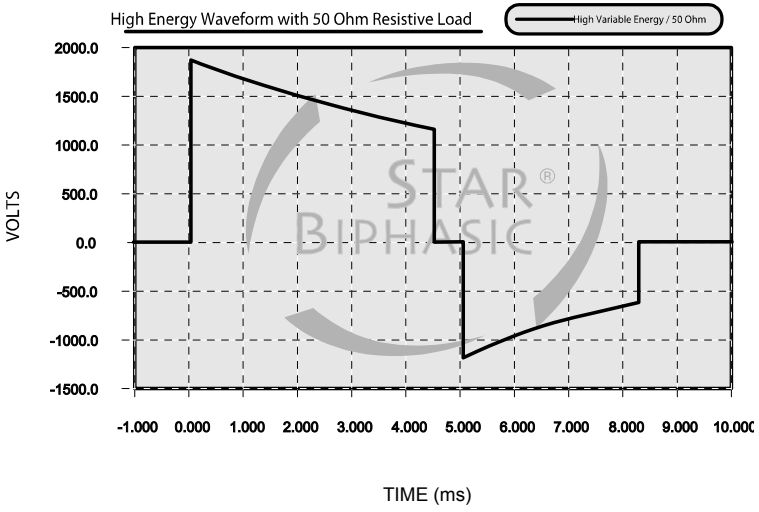
STAR BIPHASIC WAVEFORM



The STAR Biphasic Waveform is designed to measure the patient's impedance and deliver a customized shock. This allows the delivery of an optimized energy level to each patient. See table on next page for additional information.

STAR BIPHASIC ENERGY PROTOCOLS FOR RESPONDER AED

The patented STAR® Biphasic defibrillation waveform will deliver variable escalating energy that is customized to each patient's needs based upon a patient's thoracic impedance. This customization adjusts for the unique physical differences between patients. The range of impedance over which the device will deliver a shock is 20-180 Ohms. The Responder AED comes equipped with five different FDA-cleared biphasic energy protocols.

The operator, with guidance, direction and implementation from its designated AED program Medical Director, may select from one of these five protocols when placing the Responder AED into service. The Responder AED's factory default energy protocol is 200-300-300 Joule (J) escalating Variable Energy (VE). The first shock is delivered within the range of 140J-250J (200J nominal). Subsequent shocks are delivered within a range of 190J-360J (300J nominal). The accuracy of the energy for the energy in a 50-Ohm resistor is ±15%.

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Figure A1. STAR BIPHASIC WAVEFORM

Table A1 - Ultra-Low Current Responder AED Pro (all values are typical)

	Phase 1		Phase 2		
Patient's Impedance (Ohms)	Voltage (Volts)	Duration (ms)	Voltage (Volts)	Duration (ms)	Energy (Joules)
25	1390	3.3	730	3.2	145-195
50	1420	4.5	915	3.2	130-175
75	1430	5.8	980	3.2	120-160
100	1435	7.0	1020	3.2	110-150
125	1440	8.3	1040	3.2	105-140

Table A2 – Low Variable Energy Waveform Responder AED Pro (all values are typical)

	Phase 1		Phase 2		
Patient's Impedance (Ohms)	Voltage (Volts)	Duration (ms)	Voltage (Volts)	Duration (ms)	Energy (Joules)
25	1570	3.3	825	3.2	200-250
50	1600	4.5	1030	3.2	170-210
75	1610	5.8	1105	3.2	120-160
100	1615	7.0	1150	3.2	150-180
125	1620	8.3	1170	3.2	140-170

Table A3 – High Variable Energy Waveform Responder AED Pro (all values are typical)

	Phase 1		Phase 2		
Patient's Impedance (Ohms)	Voltage (Volts)	Duration (ms)	Voltage (Volts)	Duration (ms)	Energy (Joules)
25	1885	3.3	990	3.2	265-360
50	1920	4.5	1240	3.2	235-320
75	1930	5.8	1325	3.2	215-295
100	1940	7.0	1380	3.2	200-270
125	1945	8.3	1405	3.2	190-260

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These Rescue Protocols are selected by using the ServiceLink software program. The five biphasic energy protocols available are as follows:

Rescue Protocols	Shock Sequence[1]	Energy Level	Energy Range (J)
Factory Default	1.	200VE	140J-250J
	2.	300VE	190J-360J
	3.	300VE	190J-360J
Protocol #2	1.	200VE	140J-250J
	2.	200VE	140J-250J
	3.	300VE	190J-360J
Protocol #3	1.	150VE	105J-195J
	2.	200VE	140J-250J
	3.	200VE	140J-250J
Protocol #4	1.	150VE	105J-195J
	2.	150VE	105J-195J
	3.	200VE	140J-250J
Protocol #5	1.	200VE	140J-250J
	2.	200VE	140J-250J
	3.	200VE	140J-250J

SAFETY STANDARDS

IEC 60601-1 (1998), Amendments 1 (1991) and 2 (1995); IEC 60601-2-4 (2002); IEC 60601-1-4 (2000)

ELECTROMAGNETIC COMPATIBILITY REQUIREMENTS

The Responder AED meets the requirements of the following EMC standards, as required by IEC 60601-2-4.:

IEC 60601-1-2 (2001), Medical electrical equipment Part 1: General requirements for safety 2. Collateral standard: electromagnetic compatibility - Requirements and tests.

EMISSIONS

Electromagnetic Fields: CISPR 11 (2003), Industrial, scientific and medical (ISM) radio-frequency equipment - radio disturbance characteristics - limits and methods of measurement; Group 1, Class B. IEC 60601-2-4 (2002), Section 36.201.1.

IMMUNITY

Electromagnetic: IEC 61000-4-3 (2003), Electromagnetic compatibility (EMC) - part 4-3: Testing and measurement techniques - radiated, radio-frequency, electromagnetic field immunity test; Level 3 (10V/m) and X (20V/m). IEC 60601-2-4 (2002) Section 36.202.3.

Magnetic: IEC 61000-4-8 (1994), Electromagnetic compatibility (EMC) - part 4. Testing and measurement techniques - section 8. Power frequency magnetic field immunity test basic EMC publication; Level X (3 A/m). IEC 60601-2-4 (2002), Section 36.202.8.

ESD: IEC 61000-4-2 (2001), Electromagnetic compatibility (EMC) - part 4-2: testing and measurement techniques - electrostatic discharge immunity test; Level 3. IEC 60601-2-4 (2002), Section 36.202.2.

[1] The ultra-low current, low current and high current shocks are variable energy. The actual energy is determined by the patient's impedance.

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Guidance and manufacturer's declaration – electromagnetic emissions		
The AED is intended for use in the electromagnetic environment specified below. The customer or the user of the AED should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The AED uses RF energy only for its internal function. Therefore its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The AED is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
The AED is intended for use in the electromagnetic environment specified below. The customer or the user of the AED should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not applicable	
Voltage dips, short interruptions and voltage variations on power supply input lines 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Not applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	80 A/m	Power frequency magnetic fields should be at levels no higher than those characteristic of a typical location in typical heavy industrial and power plants and the control rooms of H.V. sub-stations.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

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Guidance and manufacturer's declaration – electromagnetic immunity			
The AED is intended for use in the electromagnetic environment specified below. The customer or the user of the AED should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the AED, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[a] 10 Vrms 150 kHz to 80 MHz in ISM bands[a]	Not Applicable Not Applicable	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	d = 1.2 √P 80 MHz to 800 MHz d = 2.3 √P 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m)[b]. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[c] should be less than the compliance level in each frequency range.[d] Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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[a] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 to 40.70 MHz.

[b] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

[c] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the AED is used exceeds the applicable RF compliance level above, the AED should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the AED.

[d] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the AED

The AED is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the AED can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AED as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter **W**	**Separation distance according to frequency of transmitter** m			
	150 kHz to 80 MHz outside ISM bands $d = 1.2\sqrt{P}$	**150 kHz to 80 MHz in ISM bands** $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.12	0.23
0.1	0.38	0.38	0.38	0.73
1	1.2	1.2	1.2	2.3
10	3.8	3.8	3.8	7.3
100	12	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 to 40.70 MHz.

NOTE 3 An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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FOR YOUR NOTES:

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SECTION 7: ACCESSORIES

OVERVIEW

This section contains a list of parts and software accessories for Responder AEDs. To place an order, contact your representative or distributor.

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RESPONDER AEDs

Each Responder AED package includes one automated external defibrillator, one pair of adult defibrillation pads, one disposable IntelliSense® battery, one serial communication cable, one Operator's Manual, one Service CD-ROM (with Service Manual, ServiceLink® customization software, and ServiceLink® Manual), and one RescueLink® event-review CD-ROM.

Responder AED is available in more than twenty languages, with others being added on a regular basis. For a complete list of those available, contact your GE sales representative.

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AED ACCESSORIES

PART NUMBER	DESCRIPTION
2019199-002	Defibrillation pads (adult) with two-year shelf life
2019199-003	Pediatric Defibrillation Electrodes with two-year shelf life
2019437-001	IntelliSense® Lithium battery for Responder AEDs
2022103-201	RescueLink® CD-ROM
2022102-201	ServiceLink® CD-ROM

AED DELIVERY SYSTEMS	
2019199-001	Soft-sided carrying case for Responder AED
2019615-001	Ready Kit: includes nitrile gloves, razor, scissors, towel, 4” gauze, antiseptic wipes, one way filter mask
2019199-005	AED Wall mount storage case
2019199-006	AED Wall mount storage case with strobe light alarm
2019199-004	Wall rack

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SECTION 8: CONTACT INFORMATION / CUSTOMER SERVICE

To order supplies or accessories, contact your representative or distributor. For technical support, contact your local GE customer service.
Please have the serial and model numbers available. The serial and model numbers are located on the back of the Responder AED.

Responder AED is manufactured for:

GE Medical Systems Information Technologies, Inc.
8200 West Tower Avenue, Milwaukee, WI 53223 USA
Tel.: 800 558 7044 (USA only)
Fax: 800 421 6841
Canada Tel: 800 668 0732

GE Medical Systems Information Technologies GmbH
Munzinger Str. 3, D-79111 Freiburg, Germany
Tel.: +49 761 4543 0
Fax: +49 761 4543 233

Responder AED is manufactured by:

Cardiac Science Corporation
500 Burdick Parkway
Deerfield, WI 53531, USA

CE 0086

EC REP

MDSS GmbH
Schiffgraben 41
D-30175 Hannover
Germany
Tel: +49 511 62 62 86 30
Fax: +49 511 62 62 86 33

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Responder AED

automated external defibrillator